Example of a Batch Record and explanation of its key sections

Compare the following descriptions with the illustrated Batch Record below. The areas are marked with different colors for better understanding.

Coulored Area	Description
Sodium Chloride Inject. Sol.	The name of the product: active ingredient and dosage form
Dark red	A description of the dosage form, strength of the product and batch size, proposal of label information for the finished product
Orange	A list of all starting materials* and equipment to be used including calculated quantity relating to batch size and batch quantity. This means the sum of ingredients must be equal to batch size
Yellow	Expected final yield with information on: calculated batch size, batch quantity, density, proposed shelf life Calculated quantity of the material to compound the requested batch size and sum of ingredients
Light green	Processing and methodology of compounding information, also recommended processing location and principal equipment to be used. Detailed step-wise processing instructions (check on materials, pretreatments, sequence for adding materials, mixing times, temperatures, etc.)
Green	In-process controls: Information about units produced and/or further processing, significant intermediate stages/observed deviations, dates of commencement and completion of production. Where necessary, the requirements for storage of the products, including the container, the labelling an any special storage conditions or special precautions to be observed.
Blue	Quality Control of the product: sensual tests, identity tests, physical and analytical data to be gained to release the product. The approach is on the most differentiated and practical tests with as less material as needed
Turquise	References and Information relating to the product or active ingredient, compounding information, quality controls
Lila	Names/Initials of persons responsible for production, control, release of batch

*All materials if applicable are provided with the International Nonproprietary Names INNs and CAS numbers, described using the designated name and reference that is unique to that material

OpenAPO

Label: Compounder

PHARMACY NAME Batch-Nr.

SODIUM CHLORIDE Inject.Sol.

Isotonic Normal Saline 9 mg/ml

0.9% 450 mg = 50 ml Vial

Na+ 154 micromol/ml

Cl- 154 micromol/ml

Conserv.agent 0.1% Methylparaben

308 mOsm/L Exp.Date

Date planned	
Date started	
Batch size	30 Lt
Batch quantity	600 Items of 50 ML
Density	1.0042
Shelf life	36 Months (suggested)

Product name/Conc.

Total quant./Vol./Form

Composition

Factor: 1.0000

Ingredients		Prod.Check		Quantity		Lot Number by	Weighed	Checked
A	7647-14-5-2		Sodium chloride parent.use	270.00	GM			
B	99-76-3		Methyl hydroxybenzoate	30.00	GM			
C	7732-18-5-2		Water for injections	5000.00	GM			
D	7732-18-5-2		Water for injections	24700.00	GM			
E				0.00	GM			
F				0.00	GM			
Sum of ingredients				30000.00	GM			

Materials

		Mat.Check		Piece(s)		Lot Number	Checked by
N	63711		Filter round 3µ (1118) 200mmØ	1	Pc		
O	63444		Filter round 1.2µ 200mmØ	1	Pc		
P	63762		Vials clear glass Type I 50ml	600	Pc		
Q	63142		Rubber stoppers red 19mm	600	Pc		
R	62847		Aluminiumcaps 20mm silver	600	Pc		
S	63010		Labels white 50x30mm	610	Pc		

Processing

	Adhere to SOP Nr.	Carried out by	Checked by
Prepare equipment to be utilized			
Dissolve first B and then A in C of approx. 90°C			
Fill up with D and mix for at least 10 minutes			
Filtrate across 2 membrane filters			
Fill portions of 50ml under Laminar Air Flow, add stoppers, caps & seal			
Sterilisation: 120° C / 20 min.			
Equipment cleaning			
Labelling.			

Units filled		
Units sterilised from.....to.....o'clock		
Units defective		
Units containing visible particles		
Reference & control samples		
Units gained	Total =	

Describe ev.observed deviations:

Compounding record reviewed: Date: Signed:

Quality control

Sensual tests	Aspect: clear	Odourless
	Taste: saline	Colourless

Identity tests:
1. Sodium: Yellow colour of flame
2. Chloride: 1 drop+1 drop dil.HNO_3+1 drop $AgNO_3$→white precipitate

Physical & analytical data	Minimum	Expected value	Maximum	Measured
Refractive index	1.3341	1.3345	1.3349	
pH-value	4.5	6.0	7.0	
E 250nm (1:200ml) M.paraben	0.400	0.444	0.488	
El.resistance Ohms (1:10)	0.387	0.425	0.473	

Additional tests as requested	▫ Sterility	▫ LAL	▫ other

Result of quality control	Result:	Date:	Signed

Batch record review

Batch accepted			
Batch not accepted		Date:	Signed

References (issued 09/2014)

1. Monograph
   "Bacteriostatic Sodium Chloride Injection" USP § 9.7 Ref. 10
   (Volume not larger than 30ml)
2. Formulation
   Formula collection (1994) with data elaborated at the Hospital Pharmacy of the "Institut für Spitalpharmazie" Kantonsspital Graubünden, CH-7000 Chur (Switzerland, in german)
3. Quality control
   see Nr. 1 above and WHO Basic Tests for Pharm.Dosage Forms1998, pg 63 Ref. § 9.5
   Additional data elaborated as stated under Ref. 2 above
4. Stability
   suggested 36 months at least (no analytical test results found)
5. Essential Medicines 18th ed. WHO Model List (April 2013)
   26. Solutions correcting water, electrolyte and acid.base disturbances
   26.2 Parenteral: Sodium chloride Injectable solution: 0.9% isotonic

6.1 Other monographs
-

6.2 Other formulations
-

Notice: This preparation is not for use in newborns, when containing Benzyl alcohol as a preservative in place of Methylparaben